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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,494	03/23/2004	Mark G. Resnick	SOM700/4-009(A)8CON2/6400	2768

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,494	RESNICK, MARK G.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment, terminal disclaimer and remarks all dated 2-4-05 is acknowledged.

Claims 31-53 are pending in the instant application.

Response to Arguments

Terminal disclaimers filed in response to the double patenting rejections have been entered and approved. Accordingly, the double patenting rejections of record have been withdrawn.

The following rejection of record has been maintained:

Claims 31-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatton et al (Neurology, 1996) in view of US 5,744,499 to Quash et al (hereafter Quash) OR Quash in view of Tatton et al OR unpatentable over US 5,783,606 to Tatton (Tatton '606) in view of Quash and Tatton et al.

Tatton et al teach deprenyl (same as selegiline) for reducing neuronal apoptosis caused by oxidative free radical damage and the reduction is mediated by a principal metabolite of deprenyl, desmethyldeprenyl (same as desmethylselegiline). Tatton does not teach treating a subject for photodamage skin. Tatton also fails to teach a specific enantiomer of selegiline or desmethylselegiline.

Quash teaches modulation of apoptosis (induce or suppress) as a mechanism to prevent or provide treatment for photoinduced or chronological aging of skin and other related skin conditions. Quash suggests aging of skin involves apoptosis (col. 2, lines 6-

10) and suggests compounds modulating apoptosis for preventing the appearance or signs of aging such as wrinkles. Quash also teaches that under some conditions apoptosis needs to be induced and in others apoptosis is inhibited and teaches dermatological conditions such as keratinization disorders including keratoderma, icthyosis, acne, psoriasis, eczema, epidermal or dermal hyperproliferation (col. 6 through col.7). Quash teaches the composition containing apoptosis inducer or a suppressor, in the form of a cream, patch, lotion, gel etc (col. 8) and teaches adding several additives such as moisturizes, pH regulators (col. 9). Quash does not teach selegiline or dimethyl selegiline.

Tatton '606 teaches deprenyl and desmethyldeprenyl compounds for the treatment of glaucoma (col. 3, lines 56-63). Tatton '606teaches administering deprenyl compositions in the form of sprays, liquids, gels, pastes etc., for oral, nasal, topical or other routes (col. 12).

It would have been obvious for one of an ordinary skill in the art the time of the instant invention to use the anti-apoptotic compounds (deprenyl and desmethyldeprenyl) of Tatton et al (Neurology) for inhibiting or suppressing apoptosis in several dermal or epidermal conditions such as aging because Quash teaches that skin aging basically result from malfunctioning of skin mechanisms, especially due to apoptosis and suggests any species capable of modulating apoptosis can also prevent aging and its signs such as wrinkles. Therefore, one of an ordinary skill in the art would have expected the compounds of Tatton et al to be effective in reducing or suppressing apoptosis in conditions which require modulating apoptosis i.e., psoriasis, inflammation,

keratoses, dermal or epidermal hyperproliferation (as taught by Quash). Similarly, one of an ordinary skill in the art would have incorporated the compounds of Tatton et al in the composition Quash and use for treating and/or combating photoinduced or chronologic aging of the skin by modulating apoptosis because Tatton et al suggests that the claimed compounds have the ability to reduce oxidative free radical initiated apoptosis.

Alternatively, it would have been obvious for one of an ordinary skill in the art the time of the instant invention to use selegiline or desmethylselegiline of Tatton '606 for providing or combating aging in skin by inhibiting apoptosis because Quash teaches inhibiting apoptosis provides a treatment to aging skin and Tatton et al teaches that deprenyl and desmethyldeprenyl are effective anti-apoptotic agents which reduce apoptosis caused by oxidative free radicals. Further, formulation the anti-apoptotic compositions containing deprenyl or desmethyldeprenyl, their appropriate or suitable enantiomers for effective inhibition of apoptosis, preparing the composition in the form of a spray, cream, patch etc., containing the optimum amount of the effective compound with an expectation to achieve an apoptotic effect would have been within the scope of a skilled artisan. Examiner notes that instant claim 43 recite treating a subject "for treating photodamage" where treating for photodamage is not a positive limitation. Instead, it is suggested to amend the claim to recite "A method of treating photodamaged skin in a subject".

Applicant's arguments filed 2-4-05 have been fully considered but they are not persuasive.

Applicants traverse the instant rejection and state that a skilled person would not assume that any anti-apoptotic compound could prevent aging and its sign such as wrinkles. Applicants support their position based on the teachings of Biesalski et al (Biesalski) and argue that a well-known anti-oxidant beta-carotene, an anti-apoptotic compound, has not been convincingly shown to be protective against skin damage. Therefore, applicants argue that for the same reason that an anti-apoptotic beta-carotene does not prevent aging and its signs such as wrinkles, one of an ordinary skill in the art would not expect to achieve any reduction in photodamage using any or all anti-apoptotic compound of Quash. However, the teachings of Quash suggest that apoptotic process is an underlying cause resulting in photodamage conditions, the same process which is inhibited by deprenyl (Tatton et al). Examiner notes that applicant's discovery is based on the same mechanism. Besides, it is examiner's position the effect of beta-carotene (observed in one cell type, a non-dermal cell type i.e., hepatic cell) is not an example that could be extrapolated to any apoptotic agent. On one hand, applicants argue that anti-apoptotic property of a compound does not necessarily result in reducing photodamage and at the same time applicants cite examples of the effect of claimed compounds on apoptosis in keratinocytes and interpreted the effects as "reducing photodamage". Finally, the term photodamage encompasses a wide range of skin conditions and applicants have not shown if anti-apoptotic compounds in general are not capable of reducing any or all aspects of the photodamage conditions. Alternatively, applicants have only provided evidence of the efficacy of the claimed compounds as measured by reduced apoptosis. Quash clearly

teaches modulation of apoptosis (induce or suppress) as a mechanism to prevent or provide treatment for photoinduced or chronological aging of skin and other related skin conditions. Quash suggests aging of skin involves apoptosis (col. 2, lines 6-10) and suggests compounds modulating apoptosis for preventing the appearance or signs of aging such as wrinkles. Quash also teaches that under some conditions apoptosis needs to be induced and in others apoptosis is inhibited and teaches dermatological conditions such as keratinization disorders including keratoderma, icthyosis, acne, psoriasis, eczema, epidermal or dermal hyperproliferation (col. 6 through col.7). Thus, the cited prior art also suggests that apoptotic effects of deprenyl compounds (Tatton) can be successfully used to reduce apoptosis and thus use for reducing photodamage to skin cause due to apoptosis.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala
Examiner
Art Unit 1615
May 18, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600